HEALTH POLICY

# Medicare Coverage for Patients With Diabetes

## A National Plan With Individual Consequences

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The prevalence of diabetes in the U.S. Medicare population is growing at an alarming rate. From 1980 to 2004, the number of people aged 65 or older with diagnosed diabetes increased from 2.3 million to 5.8 million. According to the Centers for Medicare and Medicaid (CMS), 32% of Medicare spending is attributed to the diabetes population. Since its inception, Medicare has expanded medical coverage of monitoring devices, screening tests and visits, educational efforts, and preventive medical services for its diabetic enrollees. However, oral antidiabetic agents and insulin were excluded from reimbursement. In 2003, Congress passed the Medicare Modernization Act that includes a drug benefit to be administered either through Medicare Advantage drug plans or privately sponsored prescription drug plans for implementation in January 2006. In this article we highlight key patient and drug plan characteristics and resources that providers may focus upon to assist their patients choose a coverage plan. Using a case example, we illustrate the variable financial impact the adoption of Medicare part D may have on beneficiaries with diabetes due to their economic status. We further discuss the potential consequences the legislation will have on diabetic patients enrolled in Medicare, their providers, prescribing strategies, and the diabetes market.

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## DIABETES: RISING MEDICARE POPULATION AND ECONOMIC BURDEN

Considered by many to be an emerging pandemic, the increasing prevalence of diabetes in the United States population over the past half-century is a growing concern. According to the Centers for Disease Control (CDC), the total number of individuals reported to have diabetes in the United States has more than doubled from 5.8 million in 1980 to 14.7 million in 2004.[1–3] Factors proposed to account for the increase of people in the United States diagnosed with diabetes include changing diagnostic criteria, improved or enhanced detection, increased awareness, growth in minority populations, obesity and lifestyle factors, and decreased mortality.[4–6]

A major increase in the prevalence and incidence of diabetes has been noted among Medicare beneficiaries age 67 or older. Between 1993 and 2001, the adjusted prevalence of diabetes cases per 1,000 individuals in the elderly Medicare population rose from 145 to 197. The highest prevalence rates were noted among minority groups. Between 1994 and 2001 the adjusted incidence of diabetes in beneficiaries age 67 or older increased 36.9%, from 27/1,000 to 37/1,000.[6] By 2050, the number of people with diabetes is expected to increase by 165%, with the greatest increase expected among individuals age 75 or older.[7]

The economic burden attributed to diabetes has paralleled population trends. According to the American Diabetes Association (ADA), in 2002 direct medical and indirect expenditures attributed to diabetes in the United States were $91.8 billion and $39.8 billion, respectively. Individuals age 65 or older bore the majority of the estimated costs at $47.6 billion. Costs for insulin and delivery supplies, oral agents to lower blood glucose, and other outpatient medications attributable to diabetes were estimated at $7.0 billion, $5.0 billion, and $5.5 billion, respectively, and represented 13% of the total health care expenditures attributable to diabetes in 2002. Costs for insulin and delivery supplies, oral agents to lower blood glucose, and other outpatient medications attributed to diabetes for individuals age 65 or older were estimated at $2.7 billion, $2.2 billion, and $2.8 billion, respectively.[8] Data suggest patients are being treated increasingly with either oral antidiabetic medications or insulin with oral antidiabetic medications instead of diet or insulin alone.[9]

## HISTORY OF MEDICARE COVERAGE FOR DIABETES

Since its inception in 1965, Medicare has covered inpatient and outpatient costs necessary for the diagnosis and treatment of illness or injury. Legislative efforts prior to 2003 have expanded Medicare coverage for diabetes management, screening, education, and supplies (Table 1). The Balanced Budget Act of 1997 (BBA) provided for coverage of blood glucose monitors and testing strips for all diabetics, addressed coverage of diabetic outpatient self-management services, and provided for outpatient diabetes self-management training (DSMT) in both hospital-based and nonhospital-based programs.[10] The BBA also authorized demonstration projects to evaluate outcomes associated with payment of coordinated care services among beneficiaries with chronic care illnesses including diabetes and telemedicine use with diabetics living in rural and inner-city areas.[11,12] The Medicare, Medicaid, and State Children's Health Insurance Program Benefits

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**Table 1. Medicare Coverage of Diabetes-Related Services and Supplies Before 2003 (Medicare Part B)**

| Services and Supplies | |
|---|---|
| Self-management Training services | Diabetes self-management training for those who are at risk for complications from diabetes<br>One hour of individual training or assessment<br>Nine hours of group training<br>Two hours of annual follow-up training<br>Beneficiaries pay 20% of the Medicare-approved amount after the yearly part B deductible |
| Diabetic supplies | Diabetic self-testing equipment and supplies for those with insulin- or noninsulin-treated diabetes<br>Self-testing equipment and supplies include glucose testing monitors, blood glucose test strips, lancet devices and lancets and glucose control solutions |
| Medical nutrition therapy services | Medical nutrition therapy services for beneficiaries with diabetes or kidney disease<br>Registered dietician or nutrition professional may provide service<br>Service includes diet counseling and therapy services to help a beneficiary manage their diabetes<br>Three hours of nutritional counseling in the first year and 2 h in subsequent years<br>Treating physician may order additional hours during the year if needed<br>Beneficiaries pay 20% of the Medicare-approved amount after the yearly part B deductible |
| Therapeutic shoes | Therapeutic shoes for beneficiaries with diabetes who meet certain criteria<br>Coverage includes depth-inlay shoes, custom-molded shoes and shoe inserts |
| Insulin pump | Insulin pumps for type 1 diabetics and some type 2 diabetics who meet diabetic control, side effect, and other criteria |
| Glaucoma screening | Glaucoma screening once every 12 mo for beneficiaries who are at high risk for glaucoma, including beneficiaries with diabetes or a family history of glaucoma<br>Beneficiaries pay 20% of the Medicare-approved amount after the yearly part B deductible |
| Foot care | Two foot exams per year, specifically for diabetic peripheral neuropathy with loss of protective sensation, provided beneficiaries have not seen a foot care professional for some other reason |

*Source: Compiled from Centers for Medicare and Medicaid (CMS) press releases.*

Improvement and Protection Act of 2000 (BIPA) provided annual glaucoma screening for individuals at high risk to develop glaucoma, individuals with a family history of glaucoma and individuals with diabetes. The link between diabetes and glaucoma remains controversial.[13] BIPA also provided for medical nutrition therapy services (MNT) for Medicare beneficiaries with diabetes and renal disease. In subsequent years, coverage decisions by the Centers for Medicare and Medicaid (CMS) have further defined DSMT and MNT guidelines and reimbursement.[14] In addition, BIPA mandated a demonstration program focused on the evaluation of disease management services combined with a prescription drug benefit in several populations of Medicare beneficiaries including those with diabetes.[15] Interspersed between these legislative efforts Medicare increased coverage of devices associated with diabetic care. In 1999, the CMS announced coverage of insulin pumps for beneficiaries with type 1 diabetes, a decision which has since been expanded to include coverage for some beneficiaries with type 2 diabetes.[16–18]

## THE MEDICARE MODERNIZATION ACT AND DIABETES

### Prescription Drug Coverage for Diabetics

The passage of the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 represents a major expansion of Medicare's coverage responsibilities to its beneficiaries (Table 2). For the first time in its history, Medicare has provided for coverage for prescription drugs, biological products and insulin, including medical supplies associated with injection. The drug coverage plan, named Medicare part D, will be administered either through prescription drug plans (PDPs) or through Medicare Advantage drug plans (MA-DPs).

The basic parameters for all PDPs are mandated. Medicare will pay 75% of all drug costs after a $250 deductible up to $2,250. Medicare will pay 0% of drug costs between $2,250 and $5,100. Beneficiaries are responsible for this "doughnut hole" in drug spending to a maximum out-of-pocket expense of $3,600. After the "catastrophic coverage" threshold is reached, enrollees will pay the greater of either 5% coinsurance or copayments of $2 for generic drugs and $5 for name brand drugs. Beneficiaries are expected to pay a premium for the benefit, estimated by the CMS at $32.20 per month in 2006. There will be premium subsidies and premium reductions for those with predetermined income and asset levels and dual-eligible individuals are covered under Medicare part D. Deductibles, limits, and thresholds are indexed to rise in future years.[19]

The Centers for Medicare and Medicaid has issued guidance for PDP formularies to include at least 2 drugs in each approved category and class.[20] This floor requirement leaves much discretion to the PDPs in terms of breadth and depth of prescription drug coverage. For example, according to the USP guidelines under the therapeutic category of blood glucose regulators, there are 3 pharmacologic classes: antihypoglycemics, oral hypoglycemics, and insulins.[21] There are a number of available insulin and insulin analog products and combinations (Table 3). It will be PDPs that negotiate with pharmaceutical companies for drug prices and subsequent inclusion or exclusion of medications on formulary. The PDPs may organize their formularies with tiers of varying drug coverage, place quantity limits on covered drugs, and institute a varying beneficiary deductible responsibility.

There are checks and balances to this system. The Centers for Medicare and Medicaid mandates that formulary and benefit structure must not discourage enrollment by certain Medicare beneficiaries and diabetes is highlighted as one of the conditions for which appropriate access is afforded to drugs.[20] Individuals may appeal for coverage of nonformulary drugs if a physician determines that all the drugs on the plan's formulary for treatment of the same condition would not be as effective or would have adverse effects for the patient. Also, a physician or authorized representative of an individual may help the beneficiary in the appeals process.

**Table 2. The Medicare Modernization Act: Expanded Medicare Coverage for Screening, Drug Therapy, Medication and Disease Management, and Demonstration Projects**

| Coverage | Implementation Date | Description |
|---|---|---|
| Initial physical | 2005 | Coverage of a 1-time preventive physical exam within 6 mo of a beneficiary's enrollment |
| Diabetes screening tests | 2005 | Coverage of diabetes screening tests, including a fasting plasma glucose test and postglucose challenges, for persons at risk for diabetes up to twice a year* Beneficiaries will not have to meet a deductible or co-pay for the test |
| Cardiovascular screening tests | 2005 | Cardiovascular screening blood tests, including tests for total cholesterol, high-density lipoprotein, and triglycerides |
| Medicare part D drug benefit | 2006† | Coverage of insulin and associated diabetic supplies (including syringes) Coverage for drugs and biological products |
| Medication therapy management | 2006 | Drug therapy management for beneficiaries with multiple chronic diseases, including diabetes, who take multiple drugs and spend more than a specified amount annually on drugs covered under the prescription drug benefit |
| Disease management programs | 2005 | Introduction of chronic care improvement initiative The CMS to select organizations to offer self-care guidance and support to chronically ill beneficiaries |
| Demonstration projects | 2005 | Beneficiaries with diabetes included in several demonstration projects designed to evaluate potential future improvements in Medicare coverage, expenditures, and quality of care |

*Source: Compiled from Centers for Medicare and Medicaid (CMS) press releases.*
**Eligible risk factors include hypertension, dyslipidemia, obesity, prior identification of impaired fasting glucose or glucose tolerance, or at least 2 of the following: overweight, family history of diabetes, history of gestational diabetes, or delivery of a baby over 9 pounds.*
*†An interim drug discount card plan introduced for 2004 and 2005.*

## Diabetes and Cholesterol Screenings Tests

The MMA provides for several preventive medicine services. Diabetes screening tests are covered in the form of either a fasting plasma glucose test and/or a postglucose challenge test up to twice a year without a deductible or co-pay. The MMA also covers an initial preventive physical to include a comprehensive examination and education regarding preven-

**Table 3. Available Insulin and Insulin Analog Products and Combinations**

| Type of Insulin | Examples | Manufacturer | Purchase Bundle | Unit Cost* ($) | Normalized Cost † ($) |
|---|---|---|---|---|---|
| Rapid-acting | | | | | |
| | Humalog (lispro) | Eli Lilly | 10 mL vial | 65.99 | 65.99 |
| | Humalog (lispro) pen | Eli Lilly | 3 mL cartridge, 5 cartridges | 152.60 | 101.73 |
| | NovoLog (aspart) | Novo Nordisk | 10 mL vial | 81.71 | 81.71 |
| | NovoLog Flexpen | Novo Nordisk | 3 mL cartridge, 5 cartridges | 149.89 | 99.93 |
| Short-acting | | | | | |
| | Humulin R | Eli Lilly | 10 mL vial | 32.23 | 32.23 |
| | Novolin R | Novo Nordisk | 10 mL vial | 32.23 | 32.23 |
| | Novolin R InnoLet | Novo Nordisk | 3 mL cartridge | 13.26 | 44.20 |
| | Novolin R PenFill | Novo Nordisk | 3 mL cartridge, 5 cartridges | 89.83 | 59.89 |
| Intermediate-acting | | | | | |
| | Humulin N | Eli Lilly | 10 mL vial | 32.23 | 32.23 |
| | Humulin N pen | Eli Lilly | 3 mL, 5 cartridges | 90.40 | 60.27 |
| | Novolin N | Novo Nordisk | 10 mL vial | 32.23 | 32.23 |
| | Novolin N Innolet | Novo Nordisk | 3 mL cartridge, 5 cartridges | 67.99 | 45.33 |
| | Novolin N pen | Novo Nordisk | 3 mL cartridge, 5 cartridges | 89.83 | 59.89 |
| | Humulin L | Eli Lilly | 10 mL vial | 32.23 | 32.23 |
| Long-acting | | | | | |
| | Humulin U (ultralente) | Eli Lilly | 10 mL vial | 32.23 | 32.23 |
| | Lantus (glargine) | Sanofi-Aventis | 10 mL vial | 73.77 | 73.77 |
| | Apidra (glulisine) | Sanofi-Aventis | | n/a‡ | |
| Intermediate- and short-acting mixtures | | | | | |
| | Humulin 50/50 | Eli Lilly | 10 mL vial | 29.35 | 29.35 |
| | Humulin 70/30 | Eli Lilly | 10 mL vial | 33.47 | 33.47 |
| | Humulin 70/30 pen | Eli Lilly | 3 mL cartridge, 10 cartridges | 191.14 | 63.71 |
| | Humalog Mix 75/25 | Eli Lilly | 10 mL vial, 2 vials | 154.63 | 77.32 |
| | Humalog Mix 75/25 pen | Eli Lilly | 3 mL cartridge, 5 cartridges | 129.99 | 86.66 |
| | Novolin 70/30 | Novo Nordisk | 10 mL vial | 33.47 | 33.47 |
| | Novolin 70/30 Innolet | Novo Nordisk | 3 mL cartridge, 5 cartridges | 67.99 | 45.33 |
| | Novolin 70/30 Penfill | Novo Nordisk | 3 mL cartridge, 5 cartridges | 97.87 | 65.25 |
| | NovoLog Mix 70/30 Flexpen | Novo Nordisk | 3 mL cartridge, 5 cartridges | 160.40 | 106.93 |
| Rapid-acting, inhaled | Exubera | Pfizer | 1 mg, 3mg blister for inhaler | n/a§ | |

Manufacturer information: Eli Lilly (Indianapolis, IN); Novo Nordisk (Bagsvasrd, Denmark); Sanofi-Aventis (Paris, France); Pfizer (New York, NY).
**Source: www.drugstore.com (accessed December 29, 2005).*
*†Cost normalized to 10 mL (100 U/mL).*
*‡Apidra approved by Food and Drug Administration in April, 2004, expected introduction in 2006.*
§Exubera approved by Food and Drug Administration in January 2006, expected introduction in 2006.

tive services. The act covers cardiovascular screening tests including tests for total cholesterol, high-density lipoprotein, and triglycerides every 5 years without deductible or co-pay.

### Disease Management Programs, Medication Therapy Management Programs, and Demonstration Projects

The MMA authorizes the development and testing of a voluntary chronic care improvement initiative aimed at improving the quality of care and life for Medicare beneficiaries living with multiple chronic illnesses. Named Medicare Health Support, the program is aimed at beneficiaries with multiple chronic conditions including complex diabetes, chronic obstructive pulmonary disease, and congestive heart failure. The Centers for Medicare and Medicaid will oversee programs operated through health care organizations chosen through a competitive selection process.[2] In 1 example of this initiative, the Joslin Diabetes Center will participate in a coalition to provide disease management services to Medicare patients in Mississippi with complex diabetes or congestive heart failure.[22]

The MMA requires all plans offering the Medicare drug benefit to have a medication therapy management program. The targeted beneficiaries for these programs include those with multiple chronic conditions including diabetes, asthma, hypertension, high cholesterol, and congestive heart failure. The goal is to ensure that drugs prescribed for these beneficiaries are appropriately used to optimize therapeutic outcomes and reduce risk of adverse events.

The MMA also includes provisions for several demonstration projects intended to test potential future improvements in Medicare coverage, expenditures, and quality of care; several of the projects focus on individuals with diabetes. For example, 1 demonstration project is focused on consumer-directed chronic outpatient services in Medicare beneficiaries with chronic conditions.[23]

## POTENTIAL MMA IMPACT ON THE DIABETES HEALTH CARE ENVIRONMENT

The MMA expands the government's responsibility for the health care of the diabetic patient. Numerous studies have demonstrated decreased compliance and increased morbidity in diabetics with reduced prescription drug coverage.[24–26] Enhanced drug coverage under the MMA may lead to improved compliance and adherence to therapy and ultimately better glycemic control and decreased morbidity in the diabetic patient. In addition, the MMA provides for enhanced screening and preventive medicine services. These efforts will likely improve physicians' ability to identify those with diabetes or at risk for developing diabetes earlier in the natural history of the disease and lead to improved control of risk factors and treatment of disease.

The economic impact of the MMA on the diabetic patient will vary depending on the patient's medication requirement, economic situation, and chosen PDP. Given that diabetic patients have, on average, more comorbid disease than nondiabetics, they have much to gain collectively in terms of drug coverage and economic savings. However, the basic prescription drug plan structure has gaps in coverage with defined out-of-pocket expenses and it is estimated that 25% of all patients will pay more for medications under the MMA.[27] There is variability among premiums, patient cost-sharing, and formulary coverage. A drug regimen for a diabetic patient with hypertension and hypercholesterolemia using 2 oral antidiabetic agents, insulin, statin, and antihypertensive (aspirin excluded from analysis) would generate several potential costs to the patient depending on his or her economic status (Table 4).

The potential positive impact of enhanced prescription drug coverage under the MMA may be offset by drug choice limitations with PDP formularies. Diabetic patients will first have to elect whether or not to enroll in a PDP depending on their prescription drug needs, availability of plans within their geographic location, formularies of medications covered by their PDP, and economic situation. Should their current medications or selected route of administration not be included in the PDP formulary, patients will either have to advocate for medication change or enter an appeals process. Thus, the impact of the MMA on diabetics' medication choice is unclear.

The introduction of the MMA adds a new level of complexity to the health care environment that will impact diabetic providers. As Medicare patients will be enrolled in different PDPs with different formularies, physicians will have to address patients' drug coverage on an individual basis, altering medication regimens based on a patient's formulary or filing appeals for uncovered drugs. Physicians may face questions from new part D enrollees as well as from those whose current prescription drug coverage may be discontinued as a result of the MMA. In addition, as medications prescribed in hospitals may be different from medications available on PDP formularies, providers will need to ensure effective transition of medical care from the inpatient to outpatient setting. Physicians of diabetic patients will be especially vulnerable to the administrative and bureaucratic burden posed by the implementation of the MMA due to the often complex and tailored drug regimens of diabetic patients.

An effective implementation of Medicare Part D is particularly challenging in certain populations. Of note, dual-eligible individuals, a 6.4 million population of the sickest and most impoverished Medicare beneficiaries, must transition from a single state Medicaid drug payment system to the multiple part D plans.[28] This population has a higher prevalence of diabetes and uses, on average, at least 10 more prescription drugs than the general Medicare population.[29] Furthermore, providing prescription drug coverage is not, in and of itself, a panacea to barriers of effective health care delivery. Previous studies suggest that independent health status and socioeconomic status factors represent barriers to medication accessibility regardless of insurance coverage.[30] Given the higher prevalence of diabetes among African American and other minority populations compared with Caucasians, strategies to improve education, screening, and management will be necessary alongside implementation of drug coverage to improve care.

The MMA may have a major impact on the future care of diabetic patients. The product pipeline for future antidiabetic agents is extensive and includes the development of alternate routes of insulin administration such as inhaled insulin and new insulin secretagogues and sensitizers. Under the MMA PDPs have 90 days to make formulary decisions for newly approved drugs and 180 days to include the drugs on their formulary. Competing forces under the MMA will shape the development and utilization of new products. On one hand, the

**Table 4. Estimated Annual Enrollee Drug Cost for Example Diabetic Drug Regimen with Medicare Part D Coverage**

| Daily drug dose | Category | Retail drug cost | Estimated Drug Cost with Medicare Part D* | | | |
|---|---|---|---|---|---|---|
| | | | Income >150% FPL; no subsidy | Income 135%-150% FPL and assets $10,000/person; $20,000/couple | Income <$135% FPL and assets $6,000/ person; $9,000/ couple or FBDE; Income >100% FPL | FBDE; Income up to 100% FPL |
| Glyburide 10 mg | Generic | 15.98 | 12.78 | 12.78 | 12.78 | 12.78 |
| Metformin-HCL 1,000 mg | Generic | 27.99 | 22.39 | 22.39 | 22.39 | 22.39 |
| Lipitor 20 mg | Brand-name | 102.99 | 82.39 | 82.39 | 82.39 | 82.39 |
| Lisinopril 20 mg | Generic | 10.99 | 8.79 | 8.79 | 8.79 | 8.79 |
| Humalog 33 units (10 mL vial, 100 U/mL) | Brand-name | 65.99 | 52.79 | 52.79 | 52.79 | 52.79 |
| Lantus 33 units (10 mL vial, 100 U/mL) | Brand-name | 73.77 | 59.02 | 59.02 | 59.02 | 59.02 |
| Total monthly drug cost | | 297.71 | 238.17 | 238.17 | 238.17 | 238.17 |
| Yearly drug cost | | 3,572.52 | 2,858.02 | 2,858.02 | 2,858.02 | 2,858.02 |
| | | | Estimated Enrollee Drug Cost with Medicare Part D† | | | |
| Enrollee co-payments† | | | 1,108.02 | 421.20 | 252.00 | 144.00 |
| Enrollee annual premium‡ | | | 386.40 | 386.40 | 0.00 | 0.00 |
| Enrollee annual deductible | | | 250.00 | 50.00 | 0.00 | 0.00 |
| Enrollee annual drug cost | | | $1,744.42 | $857.60 | $252.00 | $144.00 |

*CBO estimate 20% gross drug savings with Medicare part D. www.cbo.gov (accessed July, 2004).
†Source: www.kff.org.[19] Co-payments (assume one month supply per subscription).
‡Medicare premium estimate at $32.30 per month; sliding scale up to $32.30/month for income 135%–150% FPL.
Sources: www.drugstore.com (prices, normalized to 30 day supply) (accessed March 27, 2006).
Non-subsidy eligible (25% up to initial coverage limit; 100% up to $3,600 out-of-pocket spending, 5% above $3,600).
Income 135%–150% FPL (15% of total costs up to $5,100 catastrophic limit; $2/generic, $5/brand-name thereafter).
Income less than 135% FPL ($2/generic, $5/brand-name; no co-pays after drug costs reach $5,100).
Full-benefit dual eligible; income greater than 100% FPL ($2/generic $5/brand-name; no co-pays after drug costs reach $5,100).
Full-benefit dual eligible; income up to 100% FPL ($1/generic $3/brand-name; no co-pays after drug costs reach $5,100).
FPL, Federal Poverty Level ($9,570/individual, $12,830/couple, 2005); FBDE, full-benefit dual eligible.

current legislation precludes Medicare from negotiating drug prices with pharmaceutical companies directly. While the Congressional Budgeting Office (CBO) estimates that there will be drug savings with the implementation of the MMA, these drug price reductions are likely less than those that would ensue if the Medicare negotiated for drugs directly.[31] Given the assumption that it is the high prices of brand-name drugs that enable the pharmaceutical industry to support research and development process in the United States, research efforts will continue unabated under the MMA. However, if the efficacies of newer agents for diabetes are no different than existing agents, it is unclear if PDPs will support the likely additional costs associated with these new products. Subsequent potential decreases in drug revenue may prove a disincentive to the drug industry to develop new drugs for the diabetic patient. The shape of future diabetic care will be directed by choices made by PDP pharmaceutical & therapeutics (P&T) committees, market forces among PDPs, and the economic capability of the government to support the program.

## RECOMMENDATIONS FOR IMPROVED CARE OF THE DIABETIC PATIENT UNDER THE MMA

The MMA represents a step forward in the care of diabetic patients enrolled in Medicare. The advantages offered by enhanced reimbursement for diabetic drugs and supplies, however, will be balanced by potentially greater restrictions on physician prescribing and increased bureaucracy. Educating Medicare enrollees with diabetes about the new legislation will be critical to their care. Furthermore, the complex drug reimbursement system proposed by the MMA will necessitate greater advocacy among diabetic health care providers in order to preserve patient rights and provider independence. We believe there are several strategies that providers and patients must undertake in order to prepare for the efficient implementation of the MMA in the diabetic community.

### Early and Comprehensive Provider and Patient Education Regarding Medicare Part D

The introduction of Medicare part D will necessitate greater patient and provider education regarding numerous aspects of the MMA including PDP enrollment, potential credits, PDP characteristics, formularies, and the appeals process for uncovered drugs. Both patients and providers will need to be educated regarding paperwork, guides, and web-based systems introduced to assist Medicare beneficiaries enroll in and compare part D plans. There will be a mass of patients with information needs regarding the Medicare part D benefit and the earlier the provider and patient undertake education initiatives, the more efficient the transition under MMA will be. There are several resources available to both patients and providers (see Table 5). Additional education and implementation efforts must be launched to address the unique needs of certain populations including dual-eligible beneficiaries and minorities. In addition to basic outreach strategies, community-based initiatives involving personal interactions between providers and beneficiaries will be critical.

### Advocacy With Review of Part D Plan Formularies and Benefits

Given the expected variation in drug cost and coverage among part D plans, its will be essential for diabetic providers to review drug formularies individually and collectively. The deci-

**Table 5. Medicare Part D Resources for Patients and Providers**

| Sponsor | Resource Format | Title and/or Web Address* | Content |
|---|---|---|---|
| CMS | Website | http://www.medicare.gov/ | Portal to landscapes of local PDPs, comparison of PDPs, formulary finder, and booklet Medicare and You 2006 |
| CMS | Website | http://www.medicare.gov/medicarereform/drugbenefit.asp | Describes a 4-step process to navigating the prescription drug process |
| CMS | Website | http://www.medicare.gov/medicarereform/help.asp | Information and links for beneficiaries with limited income and resources |
| CMS | Booklet/ Website | Medicare and You (2006) http://www.medicare.gov/spotlights.asp#medicare2006 | 94-page summary of Medicare benefits, rights, and protections |
| CMS | Telephone number | 1–800 – MEDICARE (1-800-633-4227), teletypewriter, telecommunications device for the deaf, 1–877–486–2048 | Customer service line available 24/7 to answer questions |
| CMS | Website | Landscape of local plans http://www.medicare.gov/medicarereform/map.asp | Listing of Medicare advantage and stand-alone PDPs in each state |
| CMS | Web tool/ Website | Medicare prescription drug plan cost estimator http://www.medicare.gov/ (portal to site) | Tool enables individuals to enter state and drug utilization, provides comparison of plans and portal to enroll |
| CMS | Web Tool/ Website | Formulary finder http://formularyfinder.medicare.gov/formularyfinder/selectstate.asp | Tool enables individuals to enter their drugs then provides a listing of PDPs in state that include the drugs in their formularies Also includes information on drug tier level and potential restrictions |
| Eldercare, AoA | Website/ telephone number | Eldercare locator http://www.eldercare.gov/ Eldercare/Public/Home.asp, 1–800–677–1116 | Provides sources of information on senior services |
| AARP | Website | http://www.aarp.org/health/medicare/ | Information about Medicare prescription drug coverage and portal to additional resources |
| KFF | Website | http://www.kff.org/medicare/rxdrugbenefit.cfm | Portal to resources, booklets, and data regarding Medicare part D including background materials and Medicare drug calculator |
| ADA | Website | http://www.medicareinteractive.org/ | Medicare Interactive (MI) – Information about health care rights, options, and benefits offered in question and answer format Includes portal to specific information about Medicare part D |

*CMS, Centers for Medicare and Medicaid; AoA, U.S. Administration on Aging; AARP, American Association of Retired Persons; KFF, Henry J. Kaiser Family Foundation; ADA, American Diabetes Association.*
**Websites accessed on December 29, 2005.*

sion by a patient or provider to initiate an appeals process for an uncovered drug should be made in a timely fashion in order to protect the patient from paying unnecessary out-of-pocket expenses. The size of the diabetic population and the cost of treating their condition make them an especially vulnerable target to Medicare regulations and budgetary restrictions, thus there must be advocacy among patients and providers to ensure that diabetic patients have access to an acceptable standard of care with respect to depth and breadth of drug coverage.

## Future Research of the MMA Impact on the Diabetic Community

Given the numerous uncertainties regarding the implementation and impact of the MMA, there is a clear need for further studies to evaluate its impact on the diabetic patient. Studies will need to assess multiple aspects of the MMA including enrollment, patient and government expenses, and drug access. In the diabetic population, we believe particular attention should be paid to the changes in the choice of diabetic regimens resulting from implementation of the MMA as well as diabetes drug costs for Medicare and non-Medicare patients. It may also be beneficial to monitor the rate of drug development for antidiabetic medications. Outcomes research regarding the demonstration projects and medication therapy management and disease management programs introduced by the MMA will also be particularly important to the diabetic community.

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